

**Notice of Allowability**

Application No.	Applicant(s)
10/530,125	HAYASHI ET AL.
Examiner	Art Unit
Julie Ha	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Response to Non-Final filed May 29, 2007.
2.  The allowed claim(s) is/are 18-33.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*  - c)  None of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

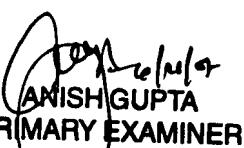
\* Certified copies not received: \_\_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

  
ANISH GUPTA  
PRIMARY EXAMINER

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Nicole Buchner on June 20, 2007.

Claims 18, 24 and 30 have been amended as follows:

18. (Currently Amended) A peptide having a formula of GLP-1 - Waa-(xaa)n-Yaa, said peptide consisting of a GLP-1 peptide and, Waa[-] connected to the GLP-1 peptide at the C-terminus of the GLP-1 peptide, (Xaa)n[-] connected to Waa, and Yaa connected to (Xaa)n (in which Waa is Arg or Lys, Xaa is Lys, n is an integer of 1 to 9, and Yaa is Arg or Arg-NH<sub>2</sub>) added to the C-terminus of the GLP-1 peptide, wherein the GLP-1 peptide is selected from the group consisting of GLP-1(7-35), [Ser<sup>8</sup>]-GLP-1(7-35), [Gln<sup>26</sup>, Asn<sup>34</sup>]-GLP-1(7-35), and [Ser<sup>8</sup>, Gln<sup>26</sup>, Asp<sup>34</sup>]-GLP-1(7-35).

24. (Currently Amended) A pharmaceutical composition for transmucosal administration containing as an active ingredient a peptide having a formula of GLP-1 - Waa-(xaa)<sub>n</sub>-Yaa, said peptide consisting of a GLP-1 peptide and, Waa[-]  
]-] connected to the GLP-1 peptide at the C-terminus of the GLP-1 peptide,  
(Xaa)<sub>n</sub>[-]-] connected to Waa, and Yaa connected to (Xaa)<sub>n</sub> (in which Waa is Arg or Lys, Xaa is Lys, n is an integer of 1 to 9, and Yaa is Arg or Arg-NH<sub>2</sub>) added to the C-terminus of the GLP-1 peptide, wherein the GLP-1 peptide is selected from the group consisting of GLP-1(7-35), [Ser<sup>8</sup>]-GLP-1(7-35), [Gln<sup>26</sup>, Asn<sup>34</sup>]-GLP-1(7-35), and [Ser<sup>8</sup>, Gln<sup>26</sup>, Asn<sup>34</sup>]-GLP-1(7-35).

30. (Currently Amended) A method for treating non-insulin dependent diabetes mellitus, insulin dependent diabetes mellitus and/or obesity which comprises transmucosally administering to the patient a pharmaceutical composition containing as an active ingredient a peptide having a formula of GLP-1 - Waa-(xaa)<sub>n</sub>-Yaa, said peptide consisting of a GLP-1 peptide and, Waa[-]-] connected to the GLP-1 peptide at the C-terminus of the GLP-1 peptide, (Xaa)<sub>n</sub>[-]-] connected to Waa, and Yaa connected to (Xaa)<sub>n</sub> (in which Waa is Arg or Lys, Xaa is Lys, n is an integer of 1 to 9, and Yaa is Arg or Arg-NH<sub>2</sub>) added to the C-terminus of the GLP-1 peptide, wherein the GLP-1 peptide is selected from the group consisting of GLP-1(7-35), [Ser<sup>8</sup>]-GLP-1(7-35), [Gln<sup>26</sup>, Asn<sup>34</sup>]-GLP-1(7-35), and [Ser<sup>8</sup>, Gln<sup>26</sup>, Asn<sup>34</sup>]-GLP-1(7-35).

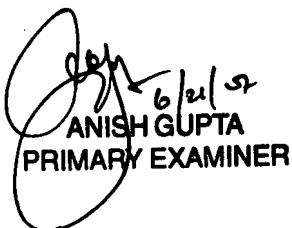
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Julie Ha  
Patent Examiner  
AU 1654

  
6/21/07  
ANISH GUPTA  
PRIMARY EXAMINER